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*Attorneys for Plaintiffs and CounterDefendants
Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

Bayer Schering Pharma AG &
Bayer HealthCare Pharmaceuticals Inc.,

Plaintiffs / Counterclaim Defendants,

v.

Mylan Pharmaceuticals Inc., Mylan Inc., and
Famy Care Ltd.,

Defendants / Counterclaim Plaintiffs.

No. 2:11-cv-00604-KJD-LRL

**Plaintiffs' Answer to Defendants'
Counterclaims**

PARTIES

3.	Admitted.
4.	Admitted.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent that Paragraph 5 is deemed to contain factual allegations, Bayer denies them.
6. Paragraph 6 contains legal conclusions to which no response is required. To the extent that Paragraph 6 is deemed to contain factual allegations, Bayer denies them.
7. Paragraph 7 contains legal conclusions to which no response is required. To the extent that Paragraph 7 is deemed to contain factual allegations, Bayer denies them.
8. Admitted.

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PATENTS IN SUIT

9. Bayer admits that Bayer Schering is the owner and assignee of United States Reissue Patent No. 37,564 (“the ’564 patent”), which is dated February 26, 2002 and is entitled “Composition for Contraception.” Bayer denies any remaining allegations in Paragraph 9.

10. Bayer admits that Bayer Schering is the owner and assignee of the ’564 patent. Bayer denies any remaining allegations in Paragraph 10.

11. Bayer admits that Bayer HealthCare is the holder of approved New Drug Application (“NDA”) No. 21-676 for YAZ® tablets, which contain as active ingredients micronized drospirenone and micronized 17 α -ethinylestradiol. Bayer admits that YAZ® is sold throughout the world. Bayer denies any remaining allegations in Paragraph 11.

12. Bayer admits that the ’564 patent appears in the FDA’s Orange Book for NDA No. 21-676. Bayer denies any remaining allegations in Paragraph 12.

13. Bayer admits that Bayer Schering is the owner and assignee of United States Patent No. 5,569,652 (“the ’652 patent”), which is dated October 29, 1996 and is entitled “Drospirenone As An Antiandrogen.” Bayer denies any remaining allegations in Paragraph 9.

14. Bayer admits that Bayer Schering is the owner and assignee of the ’652 patent. Bayer denies any remaining allegations in Paragraph 14.

15. Bayer admits that the ’652 patent appears in the FDA’s Orange Book for NDA No. 21-676. Bayer denies any remaining allegations in Paragraph 15.

16. Bayer admits that Bayer Schering is the owner and assignee of United States Patent No. 5,798,338 (“the ’338 patent”), which is dated August 25, 1998 and is entitled “Solid Dosage Forms That Contain Clathrates Of 17 α -Ethinyl Estradiol.” Bayer denies any remaining allegations in Paragraph 16.

17. Bayer admits that Bayer Schering is the owner and assignee of the ’338 patent. Bayer denies any remaining allegations in Paragraph 17.

- 1 18. Bayer admits that the '338 patent appears in the FDA's Orange Book for NDA No.
2 21-676. Bayer denies any remaining allegations in Paragraph 18.
- 3 19. Bayer admits that Bayer Schering is the owner and assignee of United States Patent
4 No. 6,787,531 ("the '531 patent"), which is dated September 7, 2004 and is entitled
5 "Pharmaceutical Composition For Use As A Contraceptive." Bayer denies any remaining
6 allegations in Paragraph 19.
- 7 20. Bayer admits that Bayer Schering is the owner and assignee of the '531 patent.
8 Bayer denies any remaining allegations in Paragraph 20.
- 9 21. Bayer admits that the '531 patent appears in the FDA's Orange Book for NDA No.
10 21-676. Bayer denies any remaining allegations in Paragraph 21.
- 11 22. Bayer admits that Bayer Schering is the owner and assignee of United States Patent
12 No. 6,933,395 ("the '395 patent"), which is dated August 23, 2005 and is entitled "Processing For
13 Producing Of Drospirenone (6β , 7β , 15β , 16β -Dimethylene-3-Oxo- 17α -Pregn-4-EN-21, 17-
14 Carbolactone, DRSP) As Well As 7α -(3-Hydroxy-1-Propyl)- 6β , 7β , 15β , 16β -Dimethylene- 5β -
15 Hydroxy." Bayer denies any remaining allegations in Paragraph 22.
- 16 23. Bayer admits that Bayer Schering is the owner and assignee of the '395 patent.
17 Bayer denies any remaining allegations in Paragraph 23.
- 18 24. Bayer admits that the '395 patent appears in the FDA's Orange Book for NDA No.
19 21-676. Bayer denies any remaining allegations in Paragraph 24.
- 20 25. Bayer admits that Bayer Schering is the owner and assignee of United States Patent
21 No. 6,958,326 ("the '326 patent"), which is dated October 25, 2005 and is entitled "Cyclodextrin-
22 Drospirenone Inclusion Complexes." Bayer denies any remaining allegations in Paragraph 25.
- 23 26. Bayer admits that Bayer Schering is the owner and assignee of the '326 patent.
24 Bayer denies any remaining allegations in Paragraph 26.
- 25 27. Bayer admits that the '326 patent appears in the FDA's Orange Book for NDA No.
26 21-676. Bayer denies any remaining allegations in Paragraph 27.

1 28. Bayer admits that Bayer Schering is the owner and assignee of United States Patent
2 No. 7,163,931 (“the ’931 patent”), which is dated January 16, 2007 and is entitled “Compositions
3 of Estrogen-Cyclodextrin Complexes.” Bayer denies any remaining allegations in Paragraph 28.

4 29. Bayer admits that Bayer Schering is the owner and assignee of the ’931 patent.
5 Bayer denies any remaining allegations in Paragraph 29.

6 30. Bayer admits that the ’931 patent appears in the FDA’s Orange Book for NDA No.
7 21-676. Bayer denies any remaining allegations in Paragraph 30.

8 31. Bayer admits that Bayer Schering is the owner and assignee of United States
9 Reissue Patent No. 38,253 (“the ’253 patent”), which is dated September 16, 2003 and is entitled
10 “Composition for Contraception.” Bayer denies any remaining allegations in Paragraph 31.

11 32. Bayer admits that Bayer Schering is the owner and assignee of the ’253 patent.
12 Bayer denies any remaining allegations in Paragraph 32.

13 33. Bayer admits that the ’253 patent appears in the FDA’s Orange Book for NDA No.
14 21-676. Bayer denies any remaining allegations in Paragraph 33.

15 34. Bayer admits that Bayer Schering is the owner and assignee of United States
16 Reissue Patent No. 37,838 (“the ’838 patent”), which is dated September 10, 2002 and is entitled
17 “Composition for Contraception.” Bayer denies any remaining allegations in Paragraph 34.

18 35. Bayer admits that Bayer Schering is the owner and assignee of the ’838 patent.
19 Bayer denies any remaining allegations in Paragraph 35.

20 36. Bayer admits that the ’838 patent appears in the FDA’s Orange Book for NDA No.
21 21-676. Bayer denies any remaining allegations in Paragraph 36.

22 37. Bayer admits that McGuire Woods LLP sent a letter to Bayer on or about March 7,
23 2011 providing notice on behalf of Mylan Pharmaceuticals, Inc. and Famy Care, Ltd. had filed
24 paragraph IV certifications for the patents listed in Paragraph 37 in conjunction with ANDA No.
25 20-2594. The remainder of Paragraph 37 contains legal conclusions to which no response is
26 required. To the extent that Paragraph 37 is deemed to contain factual allegations, Bayer denies

1 them.

2 38. Bayer admits that it asserted the '564 patent against Mylan Pharmaceuticals, Inc.,
3 Mylan, Inc. and Famy Care Ltd. in its April 19, 2011 complaint. Bayer denies any remaining
4 allegations in Paragraph 38.

5 **FIRST COUNT**

6 **(Declaratory Judgment of Invalidity of the '564 Patent)**

7 39. Bayer incorporates its above responses in response to Paragraph 39.

8 40. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
9 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint.

10 41. Bayer admits that Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd.
11 denied infringement of the '564 patent in their answer to Bayer's April 19, 2011 complaint. Bayer
12 further admits that Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. asserted as its
13 "Second Separate Defense" that "The claims of the '564 reissue patent are invalid for failure to
14 satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103,
15 112 and/or 116." To the extent that Paragraph 41 contains separate allegations than those set forth
16 in Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd.'s answer to Bayer's complaint,
17 Paragraph 41 contains legal conclusions to which no response is required. To the extent that
18 Paragraph 41 is deemed to contain separate factual allegations than those set forth in Mylan
19 Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd.'s answer to Bayer's complaint, Bayer
20 denies them.

21 42. Paragraph 42 contains legal conclusions to which no response is required. To the
22 extent that Paragraph 42 is deemed to contain factual allegations, Bayer denies them.

23 43. Denied.

SECOND COUNT

(Declaratory Judgment of Non-Infringement of the '564 Patent)

44. Bayer incorporates its above responses in response to Paragraph 44.

45. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint.

46. Bayer admits that Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. denied infringement of the '564 patent in their answer to Bayer's April 19, 2011 complaint. Bayer further admits that Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. asserted as its "First Separate Defense" that "The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594 have not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '564 reissue patent." To the extent that Paragraph 46 contains separate allegations than those set forth in Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd.'s answer to Bayer's complaint, Paragraph 46 contains legal conclusions to which no response is required. To the extent that Paragraph 46 is deemed to contain separate factual allegations than those set forth in Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd.'s answer to Bayer's complaint, Bayer denies them.

47. Paragraph 47 contains legal conclusions to which no response is required. To the extent that Paragraph 47 is deemed to contain factual allegations, Bayer denies them.

48. Denied.

THIRD COUNT

(Declaratory Judgment of Non-Infringement of the '652 Patent)

49. Bayer incorporates its above responses in response to Paragraph 49.

50. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the remaining allegations in Paragraph 50.

1 || 51. Paragraph 51 contains legal conclusions to which no response is required.

2 52. Paragraph 52 contains legal conclusions to which no response is required. To the
3 extent that Paragraph 52 is deemed to contain factual allegations, Bayer denies them.

4 53. Paragraph 53 contains legal conclusions to which no response is required. To the
5 extent that Paragraph 53 is deemed to contain factual allegations, Bayer denies them.

6 54. Paragraph 54 contains legal conclusions to which no response is required. To the
7 extent that Paragraph 54 is deemed to contain factual allegations, Bayer denies them.

8	55.	Denied.
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9 || **FOURTH COUNT**

10 **(Declaratory Judgment of Non-Infringement of the '338 Patent)**

11 56. Bayer incorporates its above responses in response to Paragraph 56.

12 57. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
13 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
14 remaining allegations in Paragraph 57.

15 58. Paragraph 58 contains legal conclusions to which no response is required.

16 59. Paragraph 59 contains legal conclusions to which no response is required. To the
17 extent that Paragraph 59 is deemed to contain factual allegations, Bayer denies them.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent that Paragraph 60 is deemed to contain factual allegations, Bayer denies them.

20 61. Paragraph 61 contains legal conclusions to which no response is required. To the
21 extent that Paragraph 61 is deemed to contain factual allegations, Bayer denies them.

22	62.	Denied.
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23 FIFTH COUNT

24 (Declaratory Judgment of Invalidity of the '531 Patent)

25 63. Bayer incorporates its above responses in response to Paragraph 63.

26 | 64. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy

1 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
2 remaining allegations in Paragraph 64.

3 65. Paragraph 65 contains legal conclusions to which no response is required.

4 66. Paragraph 66 contains legal conclusions to which no response is required. To the
5 extent that Paragraph 66 is deemed to contain factual allegations, Bayer denies them.

6 67. Paragraph 67 contains legal conclusions to which no response is required. To the
7 extent that Paragraph 67 is deemed to contain factual allegations, Bayer denies them.

8 68. Paragraph 68 contains legal conclusions to which no response is required. To the
9 extent that Paragraph 68 is deemed to contain factual allegations, Bayer denies them.

10 69. Denied.

11 **SIXTH COUNT**

12 **(Declaratory Judgment of Invalidity of the '395 Patent)**

13 70. Bayer incorporates its above responses in response to Paragraph 70.

14 71. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
15 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
16 remaining allegations in Paragraph 71.

17 72. Paragraph 72 contains legal conclusions to which no response is required.

18 73. Paragraph 73 contains legal conclusions to which no response is required. To the
19 extent that Paragraph 73 is deemed to contain factual allegations, Bayer denies them.

20 74. Paragraph 74 contains legal conclusions to which no response is required. To the
21 extent that Paragraph 74 is deemed to contain factual allegations, Bayer denies them.

22 75. Paragraph 75 contains legal conclusions to which no response is required. To the
23 extent that Paragraph 75 is deemed to contain factual allegations, Bayer denies them.

24 76. Denied.

SEVENTH COUNT

(Declaratory Judgment of Non-Infringement of the '326 Patent)

77. Bayer incorporates its above responses in response to Paragraph 77.

78. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the remaining allegations in Paragraph 78.

79. Paragraph 79 contains legal conclusions to which no response is required.

80. Paragraph 80 contains legal conclusions to which no response is required. To the extent that Paragraph 80 is deemed to contain factual allegations, Bayer denies them.

81. Paragraph 81 contains legal conclusions to which no response is required. To the extent that Paragraph 81 is deemed to contain factual allegations, Bayer denies them.

82. Paragraph 82 contains legal conclusions to which no response is required. To the extent that Paragraph 82 is deemed to contain factual allegations, Bayer denies them.

83. Denied.

EIGHTH COUNT

(Declaratory Judgment of Non-Infringement of the '931 Patent)

84. Bayer incorporates its above responses in response to Paragraph 84.

85. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the remaining allegations in Paragraph 85.

86. Paragraph 86 contains legal conclusions to which no response is required.

87. Paragraph 87 contains legal conclusions to which no response is required. To the extent that Paragraph 87 is deemed to contain factual allegations, Bayer denies them.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent that Paragraph 88 is deemed to contain factual allegations, Bayer denies them.

89. Paragraph 89 contains legal conclusions to which no response is required. To the

1 extent that Paragraph 89 is deemed to contain factual allegations, Bayer denies them.

2 90. Denied.

3 **NINTH COUNT**

4 **(Declaratory Judgment of Invalidity of the '253 Patent)**

5 91. Bayer incorporates its above responses in response to Paragraph 91.

6 92. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
7 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
8 remaining allegations in Paragraph 92.

9 93. Paragraph 93 contains legal conclusions to which no response is required.

10 94. Paragraph 94 contains legal conclusions to which no response is required. To the
11 extent that Paragraph 94 is deemed to contain factual allegations, Bayer denies them.

12 95. Paragraph 95 contains legal conclusions to which no response is required. To the
13 extent that Paragraph 95 is deemed to contain factual allegations, Bayer denies them.

14 96. Paragraph 96 contains legal conclusions to which no response is required. To the
15 extent that Paragraph 96 is deemed to contain factual allegations, Bayer denies them.

16 97. Denied.

17 **TENTH COUNT**

18 **(Declaratory Judgment of Non-Infringement of the '838 Patent)**

19 98. Bayer incorporates its above responses in response to Paragraph 98.

20 99. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
21 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
22 remaining allegations in Paragraph 99.

23 100. Paragraph 100 contains legal conclusions to which no response is required.

24 101. Paragraph 101 contains legal conclusions to which no response is required. To the
25 extent that Paragraph 101 is deemed to contain factual allegations, Bayer denies them.

26 102. Paragraph 102 contains legal conclusions to which no response is required. To the

1 extent that Paragraph 102 is deemed to contain factual allegations, Bayer denies them.

2 103. Paragraph 103 contains legal conclusions to which no response is required. To the
3 extent that Paragraph 103 is deemed to contain factual allegations, Bayer denies them.

4 104. Denied.

5 **ELEVENTH COUNT**

6 **(Declaratory Judgment of Invalidity of the '838 Patent)**

7 105. Bayer incorporates its above responses in response to Paragraph 105.

8 106. Bayer admits that it accused Mylan Pharmaceuticals, Inc., Mylan, Inc. and Famy
9 Care Ltd. of infringing the '564 patent in its April 19, 2011 complaint. Bayer denies the
10 remaining allegations in Paragraph 106.

11 107. Paragraph 107 contains legal conclusions to which no response is required.

12 108. Paragraph 108 contains legal conclusions to which no response is required. To the
13 extent that Paragraph 108 is deemed to contain factual allegations, Bayer denies them.

14 109. Paragraph 109 contains legal conclusions to which no response is required. To the
15 extent that Paragraph 109 is deemed to contain factual allegations, Bayer denies them.

16 110. Paragraph 110 contains legal conclusions to which no response is required. To the
17 extent that Paragraph 110 is deemed to contain factual allegations, Bayer denies them.

18 111. Denied.

19 **PRAYER FOR RELIEF**

20 The numbered paragraphs following the heading "Prayer for Relief" are requests for relief
21 to which no response is required. To the extent any of these numbered Paragraphs are deemed to
22 contain factual allegations, Bayer denies them.

1 Dated: September 9, 2011

2 /s/ Michael J. McCue

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18 *Bayer Schering Pharma AG and Bayer HealthCare*
19 *Pharmaceuticals Inc.*

CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(b), I certify that on September 9, 2011, I caused a true and correct copy of the foregoing to be transmitted electronically through the Court's e-filing electronic notice system to the following counsel:

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